DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

1894

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

October 22, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 07

Charles F. Woodward, DVM
Concho Dairy Consulting
620 Oak Avenue North
Onalaska, Wisconsin 54650

Dear Dr. Woodward:

On September 13, 2001, an investigator from the Food and Drug Administration (FDA) conducted an investigation involving tissue residues in cattle offered for slaughter as human food by [redacted] That investigation revealed serious deviations from the regulations for Extralabel Drug Use in Animals [Title 21, Code of Federal Regulations, Part 530 (21 CFR 530)].

Your administration of [redacted] for extra-label treatment failed to comply with the requirements in 21 CFR 530. For example, you failed to provide labeling information (e.g. withholding time) adequate to assure safe and proper drug use. Animals treated by you were subsequently offered for slaughter as human food, and the United States Department of Agriculture found flunixin meglumine residues. Thus, your deviations from 21 CFR 530 caused food to be adulterated within the meaning of 402(a)(2)(C)(ii).

We enclose a copy of 21 CFR 530 for your ready reference. We strongly suggest that you review Part 530 and become familiar with all its requirements so that you can prevent future violations of the Act.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal with a drug that was shipped in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended to be an all-inclusive list of violations. As a licensed veterinarian, you are responsible for ensuring that all drugs you prescribe and

administer are not adulterated and that all requirements of the Act are met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Also include copies of any available documentation demonstrating corrections have been made.

Your reply should be directed to Compliance Officer Carrie A. Hoffman at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

CAH/ccl

Enclosure: 21 CFR 530